

**National Cancer Institute
Institutional Review Board
AGENDA
JANUARY 13, 2014
CRC/3-1608
1:00 – 5:00 PM**

- 1. Review of Draft Minutes, December 16, 2013**
- 2. Announcements**
- 3. Old Business**
- 4. New Business**
- 5. NIH Problem Forms**
- 6. Other Expedited Actions**
- 7. Continuing Reviews**
- 8. Amendment** 11C0113-G, "A Pilot Study of Genetically Engineered NY-ESO-1 Specific (c259) T cells in HLA-A2+ Patients with Synovial Sarcoma" - Crystal Mackall, PI
- 9. Amendment** 13C0193-B, "Evaluation of 68Gallium- DOTATATE PET/CT for Detecting Primary and Metastatic Neuroendocrine Tumors" - Electron Kebebew, PI
- 10. Amendment** 12C0112-F, "Phase I Study of T Cells Expressing an Anti-CD19 Chimeric Receptor in Children and Young Adults with B Cell Malignancies" - Daniel W Lee, PI
- 11. Amendment** 11C0191-K, "A Phase 1 and Phase II Study of AZD6244 for Recurrent or Refractory Pediatric Low Grade Glioma" - Kathy Warren, PI
- 12. Initial Review** P131467, "Phase II Study of the Treatment of Metastatic Cancer that Expresses MAGE-A3 Using Lymphodepleting Conditioning Followed by Infusion of Anti-MAGE-A3 HLA-A*01 Restricted TCR-Gene Engineered Lymphocytes and Aldesleukin" - Steve Rosenberg, PI
- 13. Initial Review** P131344, "A Phase 2 Open-Label Study to Evaluate the Efficacy and Safety of VT-464 in Patients with Metastatic Castration Resistant Prostate Cancer Who Have Previously Been Treated with Enzalutamide" - Ravi Madan, PI
- 14. Initial Review** P131443, "A Pilot Study of Tremelimumab-A Monoclonal Antibody Against CTLA-4 - in Combination with Stereotactic Body Radiation Therapy (SBRT) in Patients with Advanced Pancreatic Cancer" - Austin Duffy, PI